

**PATENT COOPERATION TREATY**

**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>C1-A0402P</b>		<b>FOR FURTHER ACTION</b>	See Form PCT/IPEA/416
International application No. <b>PCT/JP2005/005790</b>	International filing date (day/month/year) <b>28.03.2005</b>	Priority date (day/month/year) <b>29.03.2004</b>	
International Patent Classification (IPC) or national classification and IPC <b>A61K48/00 (2006.01)i, A61K31/7105 (2006.01)i, A61K31/711 (2006. 01) i,</b>			
Applicant <b>SUGIYAMA, Haruo</b>			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>6</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. 1 and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> <p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>			

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

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## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2005/005790

<b>Box No. I</b> <b>Basis of the report</b>	<p>1. With regard to the language, this report is based on:</p> <p><input checked="" type="checkbox"/> the international application in the language in which it was filed</p> <p><input type="checkbox"/> the translation of the international application into _____, which is the language of a translation furnished for the purposes of:</p> <p><input type="checkbox"/> international search (Rule 12.3(a) and 23.1(b))</p> <p><input type="checkbox"/> publication of the international application (Rule 12.4(a))</p> <p><input type="checkbox"/> international preliminary examination (Rule 55.2(a) and/or 55.3(a))</p> <p>2. With regard to the elements of the international application, this report is based on (<i>replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report</i>):</p> <p><input checked="" type="checkbox"/> the international application as originally filed/furnished</p> <p><input type="checkbox"/> the description: pages _____ as originally filed/furnished pages* _____ received by this Authority on _____ pages* _____ received by this Authority on _____</p> <p><input type="checkbox"/> the claims: nos. _____ as originally filed/furnished nos.* _____ as amended (together with any statement) under Article 19 nos.* _____ received by this Authority on _____ nos.* _____ received by this Authority on _____</p> <p><input type="checkbox"/> the drawings: sheets _____ as originally filed/furnished sheets* _____ received by this Authority on _____ sheets* _____ received by this Authority on _____</p> <p><input checked="" type="checkbox"/> a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.</p> <p>3. <input type="checkbox"/> The amendments have resulted in the cancellation of:</p> <p><input type="checkbox"/> the description, pages _____ <input type="checkbox"/> the claims, nos. _____ <input type="checkbox"/> the drawings, sheets/figs _____ <input type="checkbox"/> the sequence listing (<i>specify</i>): _____ <input type="checkbox"/> any table(s) related to sequence listing (<i>specify</i>): _____</p> <p>4. <input type="checkbox"/> This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).</p> <p><input type="checkbox"/> the description, pages _____ <input type="checkbox"/> the claims, nos. _____ <input type="checkbox"/> the drawings, sheets/figs _____ <input type="checkbox"/> the sequence listing (<i>specify</i>): _____ <input type="checkbox"/> any table(s) related to sequence listing (<i>specify</i>): _____</p>
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\* If item 4 applies, some or all of those sheets may be marked "superseded."

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY		International application No. PCT/JP2005/005790																		
Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement																			
<p><b>1. Statement</b></p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Novelty (N)</td> <td style="width: 60%;">Claims <u>2, 3, 5, 6</u></td> <td style="width: 20%; text-align: right;">YES</td> </tr> <tr> <td></td> <td><u>1, 4</u></td> <td style="text-align: right;">NO</td> </tr> <tr> <td>Inventive step (IS)</td> <td>Claims _____</td> <td style="text-align: right;">YES</td> </tr> <tr> <td></td> <td><u>1-6</u></td> <td style="text-align: right;">NO</td> </tr> <tr> <td>Industrial applicability (IA)</td> <td>Claims <u>1-6</u></td> <td style="text-align: right;">YES</td> </tr> <tr> <td></td> <td>Claims _____</td> <td style="text-align: right;">NO</td> </tr> </table> <p><b>2. Citations and explanations (Rule 70.7)</b></p> <p>Document 1: T. YAMAGAMI et al., "Growth inhibition of human leukaemic cells by WT1 (Wilms' tumor gene) antisense oligodeoxynucleotides: implications for the involvement of WT1 in leukemogenesis," Blood, 1996, Vol. 87, No. 7, pages 2878 to 2884</p> <p>Document 2: WO 96/38176 A1 (Tadazo KISHIMOTO), 05 December 1996</p> <p>Document 3: WO 99/3506 A1 (Haruo SUGIYAMA), 28 January 1999</p> <p>Document 4: A. Borkhardt, "Blocking oncogenes in malignant cells by RNA interference--new hope for a highly specific cancer treatment?," 2002, Vol. 2, No. 3, pages 167 to 168</p> <p>Novelty      Claims 1 and 4</p> <p>Documents 1 to 3 describe methods for treating leukemia and/or solid tumors by using antisense DNA that is complimentary to the sense strand of WT1 or RNA that is complimentary to the transcription product of the sense strand of WT1 in order to control the expression of</p>			Novelty (N)	Claims <u>2, 3, 5, 6</u>	YES		<u>1, 4</u>	NO	Inventive step (IS)	Claims _____	YES		<u>1-6</u>	NO	Industrial applicability (IA)	Claims <u>1-6</u>	YES		Claims _____	NO
Novelty (N)	Claims <u>2, 3, 5, 6</u>	YES																		
	<u>1, 4</u>	NO																		
Inventive step (IS)	Claims _____	YES																		
	<u>1-6</u>	NO																		
Industrial applicability (IA)	Claims <u>1-6</u>	YES																		
	Claims _____	NO																		

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## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No  
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Box No. V      **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

WT1; therein, the documents indicate that the antisense DNA associated with the sense strand of WT1 is capable of inhibiting the proliferation of tumors.

Such being the case, the inventions set forth in claims 1 and 4 of the present application are disclosed in documents 1 to 3.

### Inventive Step

#### Claims 1 to 6

It would have been easy for a person skilled in the art to conceive of using RNAs instead of the antisense DNAs that are specifically mentioned in documents 1 to 3.

Meanwhile, document 4 indicates that it is possible to treat tumors by using siRNA in order to specifically inhibit the expression of a tumor gene.

As a result, the technique whereby RNAi is used to inhibit the expression of tumor genes would have been well known to a person skilled in the art of the technical field associated with pharmaceuticals prior to the priority date of the present application, as disclosed in document 4. Furthermore, it is common practice for a person skilled in the art to specify the sequence of RNAi. Such being the case, it would have been easy for a person skilled in the art to conceive of using the dsRNAs presented in documents 1 to 3, which are complimentary to the transcription product of WT1, in order to treat tumors.

Furthermore, the effects exhibited by the inventions set forth in claims 1 to 6 of the present application cannot be considered to be so significant as to have been impossible to predict in the light of documents 1 to 4.

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## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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### Supplemental Box Relating to Sequence Listing

#### Continuation of Box No. I, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of:
  - a. type of material
    - a sequence listing
    - table(s) related to the sequence listing
  - b. format of material
    - on paper
    - in electronic form
  - c. time of filing/furnishing
    - contained in the international application as filed
    - filed together with the international application in electronic form
    - furnished subsequently to this Authority for the purposes of search and/or examination
    - received by this Authority as an amendment\* on \_\_\_\_\_
2.  In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

\* If item 4 in Box No. I applies, the listing and/or table(s) related thereto, which form part of the basis of the report, may be marked "superseded."

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## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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### Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Front page

The International Patent Classification (IPC) or national classification and IPC:

A61K35/76 (2006.01)i, A61P35/00 (2006.01)i, A61P35/02 (2006.01)i